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09/357,704	07/20/1999	NEIL H. BANDER	242/024	9622
26161	7590	05/27/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			NICKOL, GARY B	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/357,704
Filing Date: July 20, 1999
Appellant(s): BANDER, NEIL H.

Laurie Butler Lawrence
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 17, 2005.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The amendment after final rejection filed on 08-16-2004 has been entered (see attached Advisory Action After the Filing of an Appeal Brief)

(5) *Summary of Claimed Subject Matter*

The summary of invention contained in the brief is correct.

(6) *Grounds of Rejection/Arguments*

(a) **Enablement.** New Claim 190, drawn to the method according to claim 69, 124, 125, 126, or 127, wherein the method of treating prostate cancer is a method that prevents or delays the progression of prostate cancer, remains rejected under 35 USC 112, 1st paragraph for the reasons of record with regards to the prevention of cancer. Appellants argue (Brief, page 5) that

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Appellant has amended the claims in the Amendment After Final filed August 13, 2004, to remove language regarding the “prevention” of prostate cancer, thereby obviating the rejection. However, since new dependent claim 190 re-inserts the language of preventing cancer, said claim is rejected for the reasons of record in the Action mailed 07-09-2004.

(b) **Written Description/New Matter.** This rejection is maintained for the reasons of record and for the reasons set forth below:

Appellants argue that the instant application provides explicit and/or implicit written description support for the disputed claim terminology of “competes for binding to prostate membrane antigen with a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and J591 monoclonal antibody” (e.g. Claim 69)

Appellants argue that the written description requirement is met if the specification shows that an Appellant was in possession of the claimed invention at the time of filing. Appellants further refer to several court decisions: *in Re Smith*, *Purdue Pharma v. Faulding, Inc.*, and *In re Wright* to conclude that that the original disclosure need not provide literal support or exact wording for claimed subject matter (Brief, page 6).

Appellants note that the claimed invention involves a method that uses an antibody having a specific feature: it competes for binding to PSMA (prostate specific membrane antigen) with a specific, disclosed antibody, namely E99, J591, J415, or J533. Appellants further provided a Declaration by Abbie Celniker under 37 CFR 1.132 which proposes that the specification, on page 27, lines 26-35, indicates that Appellant was in *possession* of antibodies that compete for binding with J415, J591, J533 or E99.

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Appellant's arguments and the Declaration have been carefully considered, but are not found persuasive. As set forth previously, the specification only provides a written description and indicates possession of a genus of antibodies that bind to the extracellular domain of PSMA and four species of such monoclonal antibodies, or *species* of the genus, e.g. E99, J591, J415, or J533.

The rejected claims, (i.e. those covering a subgenus of antibodies that "compete for binding" to E99, J591, J415, or J533) are not representative of the above genus or species because they constitute a separate subgenus of monoclonal antibodies. The specification fails to recite or reasonably contemplate or indicate possession of said subgenus. As set forth previously, it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Appellants have continued to argue that the disclosure (page 27, lines 26-35) indicates that they are in possession of all such competing antibodies. This argument has been considered previously but is not found persuasive. Appellants have further reprinted the Examiner's analysis (Brief, page 10) and argue that the disputed passage was misinterpreted because it does not rule out the use of competing antibodies. Appellants argue (page 11) that the inventor "could have used" more restrictive language such as "competing antibodies are not suitable for use in prodrug/activator systems". This argument has been considered but is not found persuasive. Although this particular passage may not necessarily exclude the use of competing antibodies, the issue is whether or not Appellants have fully described the scope of the claims; a subgenus of antibodies that compete for binding to PSMA with the species of monoclonal antibodies--- E99,

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J415, J533, and J591. In this particular case, the written description requirement for the claimed genus of antibodies that bind to the extracellular domain of PSMA are satisfied through sufficient description of a representative number of the latter species of monoclonal antibodies. However, the same cannot be said for the claimed “subgenus” of antibodies because Appellants have not identified a representative number of species that adequately describe the entire subgenus. Further, antibodies that encompass the subgenus of “competing” antibodies would include substantial variation because the disclosed species of antibodies (i.e. E99, J415, J533, and J591) include those that bind to different epitopes on the PSMA molecule. Furthermore, competing antibodies could include any antibodies that hinder binding such as those that differ in size. Thus, it cannot be said that one of ordinary skill in the art would recognize (either implicitly or explicitly) that Appellants were in possession of the claimed subgenus because the disclosure fails to describe a sufficient variety of species to reflect the variation within the subgenus.

Appellants further argue that the Examiner’s analysis was based on “unfounded assumptions or factual error” about the prodrug/activator system. Appellants further argue that no reasonable basis was presented that supports the Examiner’s view that a competing antibody would be inappropriate for the prodrug system. This argument has been considered and is not found persuasive. On the contrary, the examiner raised reasonable scientific concerns (Final Rejection, 07-09-2004, pages 3-5) regarding competing antibodies and why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the claimed subgenus. Appellants only appear to argue the opposite; that competing antibodies that bind to overlapping epitopes might just as well create the needed close proximity between the prodrug and the activator.

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Appellants further argue (Brief, page 12) that the rejection is based on a misinterpretation of the law because it relies heavily on the argument that prodrug/activator systems made with competing antibodies will not work. Appellants argue that this analysis confuses the “utility or enablement of a prodrug/activator system (which is not the subject of the claims) “with written description of the antibody components used to make the prodrug/activator system. This argument has been considered but is not found persuasive because Appellant’s alleged support of the subgenus invited the uncertainty. Further, it is not understood how the Examiner’s response was a misinterpretation of the law because the statute underlying the first paragraph of 35 USC 112 includes issues regarding enablement and written description. Moreover, the courts appear to have indicated that operability is related to complete disclosure. See MPEP 2163.05: A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir.2004) (Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing Appellant conveyed that any other coating was suitable for a PTFE dental floss.). Appellants are also reminded of the prosecution history:

(1) Appellants presented amended claims drawn to methods of treating prostate cancer comprising providing “an antibody or antigen binding portion thereof **which competes for**

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binding to prostate specific membrane antigen with a monoclonal antibody selected from the group consisting of E99, J591, J415, or J533”

(2) Based on the disclosures, the examiner could not find written support for the subgenus category of such antibodies and submitted a written description/new matter rejection.

(3) In their response, (04-14-2004, page 12) Appellants argued that the passage on page 27 lines 26-35 provided support for the disputed terminology arguing that the specification provides an embodiment where two antibodies were being described. And that it was preferable, but not necessary, that the second biological agent does not compete for binding with the first.

However, it is noted that the specification does not disclose “but not necessary”. The specification discloses “preferably one”:

“The prodrug activator is conjugated with a second biological agent according to the present invention, preferably one which binds to a non-competing site on the prostate specific membrane antigen molecule.

Thus, in reviewing this phrase, the Examiner took the position that “what is preferable” is that which one of ordinary skill in the art would commonly use or recognize in a prodrug/activator scenario, i.e. non-competing ligands, probes, or antibodies or fragments thereof. To suggest that the phrase also included “competing antibodies”, from a scientific standpoint, seemed illogical and the Examiner provided reasoning as to why there did not appear to be support in this particular scenario.

The Declaration also suggests that preferred or not, it was clear from the disclosure that the inventors were in possession of the *idea* of an antibody which competes for binding with an antibody according to the invention. The Declaration (page 3) refers to the last sentence of the

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disputed passage (page 27, last sentence) which reads: “Whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays.” However, this passage does not particularly point out nor reasonably convey whether or not Appellants were clearly in possession of a subgenus of antibodies that compete for binding to a monoclonal antibody selected from the group consisting of E99, J591, J415, or J533. In fact, the following page of the disclosure (see below and page 28, 1st paragraph) only appears to reinforce the idea that “non-competing” antibodies are the preferred embodiment for prodrug/activator conjugates.

For example, monoclonal antibodies J591, J533, and E99 bind to competing binding sites on the prostate specific membrane antigen molecule. Monoclonal antibody J415, on the other hand, binds to a binding site which is non-competing with the site to which J591, J533, and E99 bind. Thus, for example, the first biological agent can be one of J591, J533, and E99, and the second biological agent can be J415. Alternatively, the first biological agent can be J415, and the second biological agent can be one of J591, J533, and E99.

Clearly, the specification is reinforcing an established scientific principle; that in the context of the prodrug/activator conjugates, non-competing antibodies would be used. Thus, it is not clear why this passage would reasonably convey possession of a subgenus of “competing” antibodies when it’s clearly designed to convey the use of non-competing antibodies in drug conjugate scenarios.

Appellants further refer to the decisions of *In re Lukach* and *Ex parte Sorenson* (Brief, page 14), two seemingly opposing decisions with regards to a written description of a subgenus. Appellants argue (Brief, page 16) that this dispute is similar to the decision in *Ex parte Sorenson*, more so than *In re Lukach*. Appellants argue that when viewed from the prospective of implicit

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support, there is sufficient written description for the *subgenus* of antibodies that compete for binding with one of J591, E99, J415, and J533. In particular Appellants argue (page 14) that in Ex parte Sorenson the original application disclosed a broad genus of "copper complexes of carboxylic acids" as well as a number of species. Appellants further note that five working examples were from the originally unclaimed "sub-genus" of binuclear copper complexes of carboxylic acids. Four of these working examples were from the "sub-sub-genus" of binuclear copper complexes of aryl carboxylic acids' and one was from the "sub-sub-genus" of binuclear copper complexes of alkyl carboxylic acids. In summarizing the case, Appellants reiterate that the Appellant (i.e., Sorenson) sought to add a claim to the sub-genus, as well as to the two sub-subgenera. Subsequently, the examiner rejected the added sub-generic and sub-sub-generic claims for lack of implicit written description and the Board reversed relying in part on *In re Kalsow*.

Appellant's analysis and comparison of this case has been considered but is not found persuasive. On the one hand, Appellants inserted the terms "sub-genus", "sub-sub-genus", "sub-generic" and "sub-sub-generic" in describing the Board's opinion. However, none of these terms appear to have antecedent basis in the actual written opinion established by the Board (see attached Board decision). The Board appears to have based their decision on the presence of working examples. For example, with regards to binuclear copper complexes of "aryl" and or "aliphatic" carboxylic acids, the Board noted five working examples of binuclear copper complexes of carboxylic acids- four were "aryl" and one was "aliphatic". There is no recitation that these examples were member of a sub-sub-genus.

Appellants provide a review of the terminology for genus, subgenus, and species and further argue that the species of monoclonal antibodies (J591, E99, J415, and J533) fall within the broad genus of all antibodies that bind to the extracellular domain of PSMA and the relatively broad subgenus of competing antibodies. This is not found persuasive. While the four monoclonal antibodies represent species of the genus, they are not examples of species within the subgenus of “antibodies that compete for binding with one of J591, E99, J415, and J533” because members of the subgenus have yet to be discovered or produced. Thus, they cannot include the *known* species of antibodies that bind to the extracellular domain of PSMA. Thus, there is neither implicit nor explicit support for the subgenus of antibodies that compete for binding to J591, E99, J415, and J533.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. Thus, Appellant’s arguments have not been found persuasive and the rejection is maintained.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

Gary B. Nickol
May 23, 2005

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Advisory Action
After the Filing of an Appeal Brief

Application No.

09/357,704

Examiner

Gary B. Nickol Ph.D.

Applicant(s)

BANDER, NEIL H.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The reply filed 16 August 2004 is acknowledged.

1. ☐ The reply filed on or after the date of filing of an appeal brief, but prior to a final decision by the Board of Patent Appeals and Interferences, will not be entered because:
- a. ☐ The amendment is not limited to canceling claims (where the cancellation does not affect the scope of any other pending claims) or rewriting dependent claims into independent form (no limitation of a dependent claim can be excluded in rewriting that claim). See 37 CFR 41.33(b) and (c).
- b. ☐ The affidavit or other evidence is not timely filed before the filing of an appeal brief. See 37 CFR 41.33(d)(2).
2. ☐ The reply is not entered because it was not filed within the two month time period set forth in 37 CFR 41.39(b), 41.50(a)(2), or 41.50(b) (whichever is appropriate). Extensions of time under 37 CFR 1.136(a) are not available.

Note: This paragraph is for a reply filed in response to one of the following: (a) an examiner's answer that includes a new ground of rejection (37 CFR 41.39(a)(2)); (b) a supplemental examiner's answer written in response to a remand by the Board of Patent Appeals and Interferences (37 CFR 41.50(a)(2)); or (c) a Board of Patent Appeals and Interferences decision that includes a new ground of rejection (37 CFR 41.50(b)).

3. ☒ The reply is entered. An explanation of the status of the claims after entry is below or attached.
4. ☒ Other: Attachments: Examiner's Answer

Claims 69-80, 124-127, 129-130, 136-173, 186, and 190 are pending.



GARY B. NICKOL, PH.D.
PRIMARY EXAMINER

FULL TEXT OF CASES (USPQ2D)

All Other Cases

Ex parte Sorenson (BdPatApp&Int) 3 USPQ2d 1462 (5/28/1987)

Ex parte Sorenson (BdPatApp&Int) 3 USPQ2d 1462

Ex parte Sorenson

**U.S. Patent and Trademark Office, Board of Patent Appeals and
Interferences
3 USPQ2d 1462**

Opinion dated May 28, 1987

Appeal No. 640-98

Headnotes

PATENTS

1. Patentability/Validity — Adequacy of disclosure [Enablement] — (§ 115.11)

Erroneous use of term "amines," when person having ordinary skill in art would have understood proper term to be "imines," is not sufficient to show that inventor did not have possession of that subject matter.

2. Patentability/Validity — Adequacy of disclosure [Enablement] — (§ 115.11)

Specification disclosure that presented five working examples of binuclear copper complexes of carboxylic acids, as well as pictorial representations thereof, reasonably conveys to skilled artisan that inventor had possession of that subject matter.

Case History and Disposition:

Application for patent by John R. J. Sorenson, Method for Treating Convulsions with Organic Copper Compounds, Serial No. 344,309, filed February 1, 1982, continuation of Serial No. 154,132, filed May 29, 1980. From decision refusing to allow claims 25 through 27. Reversed.

Attorneys:

Harry C. Jones, III, Jennifer Gordon, and Pennie & Edmonds, New York, N.Y., for appellant.

Judge:

Before Winters, Steiner, and W. Smith, Examiners-in-Chief.

Opinion Text**Opinion By:**

Winters, Examiner-in-Chief.

Appeal from the examiner's decision refusing to allow claims 25 through 27. Claims 22 through 24 and 36 stand allowed. Claims 28, 31 through 35 and 37 through 39, which are the only other claims remaining in this application, stand objected to as depending from a rejected claim.

Claim 25 is representative:

25. A method of treating convulsive tremors or convulsive seizures comprising administration to mammals of a therapeutically effective amount of an organic compound of copper having anticonvulsive activity selected from copper complexes of imines and binuclear copper complexes of carboxylic acids, or mixtures thereof.

The examiner does not rely on any prior art references. Nor does he set forth a prior

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art rejection. Rather, the sole issue presented for review is whether the examiner correctly rejected claims 25 through 27 under 35 USC 112, first paragraph, as not adequately supported by a written description in the specification.

OPINION

We shall not sustain this rejection.

Having reviewed the rejection in light of the opposing arguments of record, we agree with appellant that the claimed subject matter is adequately supported in appellant's specification disclosure and, therefore, that the appealed claims comply with 35 USC 112, first paragraph. Essentially, we are in full agreement with the position set forth by appellant in his Brief. We shall therefore adopt that position as our own, adding the following remarks for emphasis only.

The examiner brings to our attention the following recitations in the claims on appeal: (1) "copper complexes of imines", (2) "binuclear copper complexes of carboxylic acids", and (3) "a binuclear copper complex of an aliphatic carboxylic acid or binuclear copper complex of an aryl carboxylic acid".

Focusing on the written description requirement of 35 USC 112, first paragraph, the examiner takes the position that those recitations do not appear in appellant's original disclosure and, moreover, that they are not adequately supported by the examples in the specification disclosure.

The examiner does not deny that appellant's specification supports the broad expressions "an organic compound of copper", "copper complexes of carboxylic acids", the "copper complex of an aliphatic carboxylic acid", and the "copper complex of an aryl carboxylic action". Rather, the examiner asserts that appellant's specification disclosure does not support the above-noted, narrower expressions. We recognize that, under certain circumstances, the description requirement of 35 USC 112, first paragraph may operate to defeat the patentability of a narrow but not a broader claim. *In re Smith*, 458 F.2d 1389, 173 USPQ 679 (CCPA 1972). By the same token, we are mindful that appellant's specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement. *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978). The test is whether the originally filed

specification disclosure *reasonably* conveys to a person having ordinary skill that applicant had possession of the subject matter later claimed. *In re Kaslow*, 707 F.2d 1366, 217 USPO 1089 (Fed. Cir. 1983). By the very nature of the inquiry under this statutory provision, each case turns on its own specific facts. *In re Edwards*, 568 F.2d at 1352, 196 USPO at 467. As stated in *In re Wilder*, 736 F.2d 1516, 222 USPO 369 (Fed. Cir. 1984), the inquiry into whether the description requirement is met must be determined on a case by case basis and is a question of fact. Moreover, the examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in appellant's specification disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 191 USPO 90 (CCPA 1976).

Here, the examiner states that the claim expressions at issue "do not appear in the original disclosure", which means to say that they do not find literal support therein. See the Examiner's Answer, page 2. Further, the examiner states, the expressions "are not adequately supported by the few specific compounds in the specification". Again, see the Examiner's Answer, page 2. Based on those pronouncements, the examiner concludes that appellant's claimed subject matter is not supported by a written description in the specification as filed. Quite clearly, however, the examiner has not met his initial burden of presenting evidence why a person having ordinary skill in the art would not recognize in appellant's specification a description of the invention defined by the claims. *In re Wertheim, supra*. Furthermore, the only reasoning presented which we can discern is an example of *ipse dixit* reasoning, resting on a bare assertion by the examiner.

[1] With respect to the claim recitation "copper complexes of imines", we agree with appellant that his originally filed disclosure reasonably conveys to a person having ordinary skill in the art that he had possession of that subject matter. Although appellant originally used the term "copper complexes of amines", we find that the skilled artisan would have understood this to be an inadvertent error and that "copper complexes of imines" was intended. In this regard, note particularly Table VIII of the original disclosure which lists working examples of imines falling within the scope of appellant's invention. Reading the original disclosure as a whole, as we must, we find it clear that "amines" was error, that "imes" was intended, and that this error would have been understood by a person having ordinary skill in the art.

[2] With respect to the claim recitations "binuclear copper complexes of carboxylic acids", a "binuclear copper complex of an aliphatic carboxylic acid", and "a binuclear

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copper complex of an aryl carboxylic acid", we again agree with appellant that his originally filed disclosure reasonably conveys to the skilled artisan that he had possession of that subject matter. As pointed out by appellant in his Brief, the specification disclosure as filed presents five working examples of binuclear copper complexes of carboxylic acids. Four of those are representative of a binuclear copper complex of an aryl carboxylic acid and one is representative of a binuclear copper complex of an aliphatic carboxylic acid. Note particularly the pictorial representation in Figure I, page 7 of the specification as filed. Given those working examples together with the broader disclosure of copper complexes of carboxylic acids, both aliphatic and aromatic, we have no doubt that appellant's disclosure *reasonably* conveys to the skilled artisan that appellant had possession of the subject matter now claimed.

For the reasons stated in appellant's Brief, as amplified above, the examiner's decision refusing to allow claims 25 through 27 is reversed.

REVERSED.

- End of Case -

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